Docket No.: 2294-0119PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Marta GUERRERO et al.

Application No.: 10/588,377 Confirmation No.: @@@

Filed: August 2, 2006 Art Unit: N/A

For: HYPOCHOLESTEROLEMIC COMPOSITIONS COMPRISING A STATIN AND AN ANTIFLATULENT AGENT Examiner: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT
(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

☒ a. Copies of cited U.S. patents and patent application publications are not included. Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☒ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☐ d. OTHER - The following additional information is provided for the Examiner's consideration.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☒ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☐ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ **a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or**

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

☐ The required fee is listed on the attached Fee Transmittal.

☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: NOV 2 2006

Respectfully submitted,

By _____

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Attachment(s):

☒ PTO-SB08
☒ Documents
☒ Foreign Search Report
☐ Fee
☐ Other:

PTO/SB/08A/B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	10/588,377
Filing Date	August 2, 2006
First Named Inventor	Marta GUERRERO
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	2294-0119PUS1

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-4,231,938-A	11-04-1980	Monaghan et al.	
	AB*	US-4,739,073-A	04-19-1988	Kathawala	
	AC*	US-5,273,995-A	12-28-1993	Roth	
	AD*	US-5,177,080-A	01-05-1993	Angerbauer et al.	
	AE*	US-RE37,314-E	08-07-2001	Hirai et al.	
	AF*	US-4,444,784-A	04-24-1984	Hoffman et al.	
	AG*	US-4,346,227-A	08-24-1982	Terahara et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] *(if known)*	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
	BA	EP-0 304 063-A2	02-22-1989			√
	BB	WO-2004/021972-A2	03-18-2004			√
	BC	WO-03/086387-A1	10-23-2003			√
	BD	WO-03/057195-A1	07-17-2003			√
	BE	WO-03/074034-A1	09-12-2003			√
	BF	EP-1 297 825-A1	04-02-2003			√
	BG	WO-95/01780-A1	01-19-1995			√

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	CA	Rebecca G. BAKKER-ARKEMA et al.; Safety profile of atorvastatin-treated patients with low LDL-cholesterol levels; Atherosclerosis, 149, pp. 123-129, 2000.	
	CB	Atorvastatin Calcium, LIPITOR; 1998, XP002102056 page 1.	
	CC	Stephen J. BOCCUZZI, PhD., et al.; Long-Term Safety and Effiicacy Profile of Simvastatin; American Journal of Cardiology; Vol. 68, No. 11, pp. 1127-1131, 1991 XP009032973.	
	CD	Frederick P. ZELLER et al.; Lovastatin for Hypercholesterolemia; Drug Intell. Clin. Pharm., No. 22, 1988, pp. 542.	
	CE	Edward L. POSVAR, MD, FCP et al.; Tolerance and Pharmacokinetics of Single-Dose Atorvastatin, a Potent Inhibitor of HMG-CoA Reductase, in Healthy Subjects; J. Clin. Pharmacol, No. 36, pp. 728-731, 1996.	
	CF	Bakker-Arkema et al.; Safety profile of atorvastatin-treated patients with low LDL-cholesterol levels; Atherosclerosis, March, 2000, 149(1), 123-0, PubMed. 10704623.	
	CG	BOCCUZZI et al.; Long-term safety and efficacy profile of simvastatin; Am. J. Cardiol.,	

Examiner Signature		Date Considered	

PTO/SB/08A/B (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

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Filing Date	August 2, 2006
First Named Inventor	Marta GUERRERO
Art Unit	N/A
Examiner Name	Not Yet Assigned
Attorney Docket Number	2294-0119PUS1

		November 1, 1991, 68(11), 1127-31 (Pubmed 1951069.	
	CH	BLACK et al.; An overview of the clinical safety profile of atorvastatin (lipitor), a new HMG-CoA reductase inhibitor; Arch Intern Med; March 23, 1998, 158(6), 577-84, (PubMed 9521221).	
	CI	POSVAR et al.; Tolerance and pharmacokinetics of single-dose atorvastatin, a potent inhibitor of HMG-CoA reductase, in health subjects; J. Clin Pharmacol, August, 1996, 36(8), 728-31; PubMed 8877677.	
	CJ	ZELLER et al.; Lovastatin for hypercholesterolemia; Drug Intell Clin Pharm; July-August, 1988, 22(7-8), 542-5 (PubMed 3046888).	
	CK	Donald M. BLACK, MD et al.; An Overview of the Clinical Safety Profile of Atorvastatin (Lipitor), a New HMG-CoA Reductase Inhibitor; Arch Intern Med. Vol. 158, March 23, 1998, p. 577.	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	